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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,922	04/16/2001	Fang Liang Zhang	CN01167K	9049

24265 7590 08/25/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,922

Applicant(s)

ZHANG ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 5/16/03 in Paper No: 12. Applicant has cancelled claims 1-3. Claims 4-18 are currently pending. Claims 4-11 are withdrawn from further consideration because they are drawn to non-elected invention. Claims 12-18 have been added and are under consideration.
2. The change of title is acknowledged.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed 16 May 2003 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 101

6. Claims 12-18 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record as applied to claims 1-3 in Paper No: 10.

Applicants assert that their identification of SP 168 receptor ligands is useful in that these ligands permit methods for identifying SP 168 receptor agonist and antagonists that would be useful for treating SP168-receptor related conditions. Based on the putative expression of SP168 receptor in human brain and spinal tissue Applicants further assert that SP168 receptor appears to be involved in neurodegenerative disorders such as Parkinson's, Huntington's, ALS, MS and

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Alzheimer's (see specification, page 2, 1st paragraph). Applicant contends that they have demonstrated by *in situ* hybridization the disease-related tissue "tended to exhibit lower hybridization signals" for SP168 than did normal tissue (see specification, page 29, lines 30-36). Thus, they assert that a nexus between expression of SP168 receptor and specific medical conditions has been established and provides for a specific and substantial utility. This argument is not persuasive. Even, if there was a lower hybridization signal in the disease related tissue, there is no evidence to indicate that SP 168 receptor of the instant invention is involved in any of the asserted neurodegenerative diseases. The mere presence of lower amount of the message alone does not teach anything with respect to the role of this receptor in the modulation of the disease process. Neither the specification nor the prior art has established the functional relationship of this receptor to the asserted neurodegenerative disease processes. Additionally, there is also no evidence to suggest that the level of the SP168 protein is also lower in parallel with the reduced amount of the message. Lastly, one skilled in the art would not be able predict the role of SP 168 protein in any of the above described neurodegenerative diseases based on the disclosed hybridization information. To employ the instant invention to identify agonist and /or antagonists to treat any of the disclosed diseases would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability.

The disclosed property of the claimed receptor, differential expression pattern in normal and disease tissues does not provide a specific, substantial and credible utility

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for the claimed methods. Lower hybridization signal of the disclosed receptor polypeptide in disease tissue does not establish a nexus between the receptor protein and neurodegenerative diseases. The lower expression of the message of the receptor polypeptide could just as likely be a result of the disease, and not a causative agent, therefore one of ordinary skill in the art could not target the claimed receptor for treatment of the neurodegenerative diseases. The instant specification fails to teach that the receptor polypeptide is diagnostic for any specific neurodegenerative diseases, as it is found in normal and diseased tissue and there is no evidence that a statistical difference in expression levels occurs in the diseased state.

Further, in response to Applicant's arguments with reference to Ji et al. reference, there is no dispute in agreeing that SP168 receptor is a G-protein coupled receptor. It is also clear that the G protein-coupled receptor subfamilies show diverse modes of ligand binding and physiological functions. However, one skilled in the art would not know the specific and substantial utility or function of human SP168 receptor protein, even if it was putative G protein coupled receptor because neither the prior art nor the specification provides for the asserted utility of the instant invention. In addition, evidence presented by Hollopeter et al. although not arguing against this receptor being involved in the neurodegenerative process does not provide any evidence to support Applicant's assertion.

Since the instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claim Rejections - 35 USC § 112

7. Rejection of claims 12- 18 under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention is maintained for those reasons given above in paragraph 6, with regard to the rejection of these claims under 35 U.S.C. §101.

8. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JSS

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud